



WHO Prequalification of Diagnostics: Fast Track Procedure Information for Manufacturers

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1. Introduction

The World Health Organization (WHO) Prequalification of Diagnostics Programme is coordinated through the Diagnostics and Laboratory Technology Team (DLT), in the department of Essential Health Technologies (EHT). The aim of the WHO Prequalification of Diagnostics Programme is to promote and facilitate access to safe, appropriate and affordable diagnostics of good quality in an equitable manner. Focus is placed on diagnostics for high burden diseases and their suitability for use in resource-limited settings.

The WHO Prequalification of Diagnostics Programme undertakes a comprehensive assessment of the submitted products through a standardized procedure which is based on WHO Prequalification requirements. The Prequalification of diagnostics process includes three main components:

- review of an application form and product dossier;
- laboratory evaluation of the product; and
- inspection of the manufacturing site(s).

Another element of the WHO Prequalification of Diagnostics Programme is the strengthening of the regulatory capacity of WHO Member States to improve pre- and post-market regulatory oversight of diagnostics.

The findings of the WHO Prequalification of Diagnostics Programme are used to provide technical information principally to other United Nations (UN) agencies, but also to WHO Member States and other interested organizations, on particular diagnostic technologies.

The Prequalification status of diagnostics, in conjunction with other procurement criteria, is used by UN agencies, WHO Member States and other interested organizations to guide their procurement of diagnostics.

Prequalification does not imply any approval by WHO of the diagnostic products and manufacturing site(s) in question (which is the sole prerogative of National Regulatory Authorities). Moreover, Prequalification does not constitute any endorsement or warranty by WHO of the fitness of any product for a particular purpose, including its safety and/or efficacy in the diagnosis of specific diseases.

2. Intended Audience

This document provides information on the fast track procedure to manufacturers and applicants submitting diagnostic products to the WHO Prequalification of Diagnostics Programme. In addition, the document may also be useful for end users, procurement agencies and national regulatory authorities in low- and middle income countries.

3. Definitions

National Regulatory Authority: Is a government agency or other entity that exercises a legal right to control the use or sale of diagnostics within its jurisdiction, and may take enforcement action to ensure that diagnostics marketed within its jurisdiction comply with legal requirements.

Conformity Assessment: is the systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the National Regulatory Authority, to determine

that a diagnostic is safe and performs as intended by the manufacturer and, therefore, conforms to the *Essential Principles of Safety and Performance of Medical Devices*.¹

Conformity Assessment Body (CAB): is a body engaged in the performance of procedures for determining whether the relevant requirements in technical regulations or standards are fulfilled. A CAB is authorized to undertake specified conformity assessment activities by a National Regulatory Authority.

Evidence: is considered to be the types of documentation including but not limited to, certificates, certified authorizations, licences and reports that provide proof of previous recognised regulatory review.

4. What is Fast Tracking?

A number of diagnostics submitted for prequalification may have been previously assessed through a comprehensive regulatory review process (that is, conformity assessment) to demonstrate compliance with specific requirements imposed by on or more National Regulatory Authorities. Regulatory approval is aimed at seeking assurances that the product is of quality, is safe, and performs in the country/countries associated with that regulatory approval. As such, the goals of regulation and of prequalification are very similar.

Prior regulatory approval can play an important role in facilitating the WHO prequalification assessment. Where common activities are identified between the WHO prequalification procedure and the conformity assessment procedures undertaken in achieving regulatory approval, the potential exists for WHO to fast track the prequalification procedure for that particular product. The aim of fast tracking is to avoid duplication of effort and to reduce the time to prequalify a product.

WHO will review applications for prequalification and consider each application's eligibility for fast tracking. The decision by WHO to fast track an application is based on a number of factors, and as such is made on a case-by-case basis. A prime factor is the provision of suitable evidence of prior acceptable regulatory approval of the product version submitted for prequalification. Depending on the level of evidence provided in the application relating to previous regulatory approval, WHO may then expedite the prequalification process by:

- Only reviewing in depth those aspects of the submitted product dossier that are specific or essential to the WHO Prequalification for Diagnostics programme, and/or
- Conducting a shortened inspection focused on aspects related to the prequalification of diagnostics procedure customer-based perspective, and/or
- Conduct a shortened laboratory evaluation.

WHO will always undertake assessment of the product and its production because, although regulatory approval provides a level of assurance relating to the quality, safety and performance in countries where the product is approved, it cannot always provide the same assurance when the product is used in a WHO Member State. As such, those aspects of the product and its production that impact on quality, safety and performance when used, for example, by a health care worker in a WHO Member State, must be reviewed in detail by WHO because of the uniqueness of this setting.

¹ The Global Harmonization Task Force document GHTF/SG1/N41 R9:2005 can be used as guidance document providing requirements of safety and performance. This document can be accessed through the following website: <http://www.ghtf.org/sg1/sg1-final.html>
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5. The Fast Track Procedure

5.1. Regulatory approval considered by WHO for the purposes of fast tracking

An application accepted for prequalification assessment may be considered for fast tracking if the product has been approved by a National Regulatory Authority (and their designated conformity assessment bodies), which has been recognized by WHO for these purposes. The bodies are:

- Competent Authorities from the 27 Member States of the European Union who are responsible in Europe for the oversight of the Directive 98/79/EC on in vitro diagnostic medical devices, and the associated Conformity Assessment Bodies (Notified Bodies),
- Food and Drug Administration of the United States of America,
- Health Canada and the associated conformity assessment bodies (CMDCAS Registrars),
- Japanese Ministry of Health, Labour and Welfare , and
- Therapeutic Goods Administration, Australia .

These bodies have been identified on the basis of their established regulatory capacity with respect to in vitro diagnostic medical devices, and the alignment and standard of the regulatory activities when compared to the WHO prequalification procedure, that each of these bodies undertakes.

5.2. Acceptable evidence for fast tracking

Only specific evidence issued by these National Regulatory Authorities or their designated conformity assessment bodies can be considered in fast tracking, depending on the product for prequalification. The evidence has been identified based on its utility and on the degree of commonality with the Prequalification of Diagnostics Programme requirements. **Table 1 "Evidence of Previous Regulatory Approval considered for the Fast Track Procedure"** identifies the evidence that may be used as the basis considered for fast tracking of the WHO prequalification procedure if a diagnostic has had previous regulatory approval.

In some cases, a diagnostic product may have multiple regulatory approvals and more than one of the different types of evidence identified. Each of these approvals may support different aspects of the WHO requirements, further facilitating the fast tracking of the review process. Therefore, it is important to submit to WHO all available evidence of previous regulatory approvals as requested in PQDx_018 "Instructions for Compilation of a Product Dossier" Section 10 "Regulatory History".

Table 1 "Evidence of Previous Regulatory Approvals Considered for Fast Tracking"

Product Regulatory Authority	HIV Rapid Diagnostic Tests, HIV Immunoassays & HIV NAT for diagnostic purposes	Malaria Rapid Diagnostic Tests	HIV Viral Load Assays	CD4 Assays and Related Instrumentation
European Union	EC Full Quality Assurance Certificate	IVDD NB ISO 13485:2003 Certificate	EC Full Quality Assurance Certificate	IVDD NB ISO 13485:2003 Certificate
	EC Production Quality Assurance Certificate		EC Production Quality Assurance Certificate	
	EC Type-Examination Certificate		EC Type-Examination Certificate	

Food and Drug Administration , United States of America (FDA)	Premarket Approval Application (PMA) Approval letter	510(k) Clearance letter	Premarket Approval Application (PMA) Approval letter	510(k) Clearance letter
	Biologics License Application (BLA) License		Biologics License Application (BLA) License	
Health Canada	Medical Device Licence and summary report for a Class IV IVD	Medical Device Licence and summary report for a Class III or IV IVD	Medical Device Licence and summary report for a Class IV IVD	
	CMDCAS issued ISO13485 Certificate	CMDCAS issued ISO13485 Certificate	CMDCAS issued ISO13485 Certificate	CMDCAS issued ISO13485 Certificate
Japanese Ministry of Health, Labour and Welfare (JMHLW)	*JMHLW License for Mfr (seizo-gyokyo)	*JMHLW License for Mfr (seizo-gyokyo)	*JMHLW License for Mfr (seizo-gyokyo)	*JMHLW License for Mfr (seizo-gyokyo)
	*JMHLW Recognised Foreign Manufacturer (gaikoku seizogyosya nintei)	*JMHLW Recognised Foreign Manufacturer (gaikoku seizogyosya nintei)	*JMHLW Recognised Foreign Manufacturer (gaikoku seizogyosya nintei)	*JMHLW Recognised Foreign Manufacturer (gaikoku seizogyosya nintei)
	*JMHLW Minister's Approval (shonin)	*JMHLW Minister's Approval (shonin)	*JMHLW Minister's Approval (shonin)	*JMHLW Minister's Approval (shonin)
Therapeutic Goods Administration (TGA), Australia	TGA License for Manufacture	TGA License for Manufacture	TGA License for Manufacture	TGA License for Manufacture
	TGA Issued ISO 13485 Certificate	TGA Issued ISO 13485 Certificate	TGA Issued ISO 13485 Certificate	TGA Issued ISO 13485 Certificate
	AUST R Number		AUST R Number	
	TGA Full Quality Assurance Certificate (inc I Pt 1.6)	TGA Full Quality Assurance Certificate	TGA Full Quality Assurance Certificate	TGA Full Quality Assurance Certificate
	TGA Type-Examination Certificate	TGA Type-Examination Certificate	TGA Application Audit Report	
	TGA Production Quality Assurance Certificate	TGA Production Quality Assurance Certificate	TGA Production Quality Assurance Certificate	

“NAT”

Nucleic acid amplification test

“EC”

European Commission

“ISO 13485:2003”

International Organization for Standardization: Medical devices -- Quality management systems -- Requirements for regulatory purposes Standard

“IVDD NB”

A notified body formally recognised by European Competent Authorities to carry out the conformity assessment procedures, described in the In Vitro Diagnostic Medical Devices Directive (98/79/EC), applied by a manufacturer of an in vitro diagnostic device.

“CMDCAS”

Canadian Medical Devices Conformity Assessment System-recognized conformity assessment bodies

“AUST R number” The number assigned to a product once it has been approved and registered on the Australian Register of Therapeutic Goods (ARTG).

5.3. Fast Tracking and Fees

The advantage of fast tracking is a shorter WHO prequalification procedure. There is no fee reduction associated with the fast track procedure of an application prioritized for prequalification.

6. References

- European Commission website – IVD Directive 98/79/EC
http://ec.europa.eu/enterprise/policies/european-standards/documents/harmonised-standards-legislation/list-references/iv-diagnostic-medical-devices/index_en.htm
- European Commission website - Notified Bodies recognised for the purposes of the IVD directive (97/79/EC)
http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=directive.notifiedbody&dir_id=20&type_dir=NO%20CPD&pro_id=99999&prc_id=99999&ann_id=99999&prc_ann_id=99999
- FDA Website
www.fda.gov
- Health Canada Website
<http://www.hc-sc.gc.ca/index-eng.php>
- Japan Ministry of Health, Labour and Welfare website
<http://www.mhlw.go.jp/english/index.html>
- Therapeutic Goods Administration Website
<http://tga.gov.au/>